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EXAMINER

STRZELECKA, TERESA E

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 05/20/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/919,758

Applicant(s)

LIANG ET AL.

Examiner

Teresa E Strzelecka

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3 and 5-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-45 is/are rejected.
- 7) ☒ Claim(s) 13, 26 and 42 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election with traverse of Group III (claims 21-29 and 38-45) in Paper No. 9 is acknowledged. The traversal is on the ground(s) that claims of Group II and III are generic to claims of Group I. This is found persuasive and all claims will be examined together. Therefore claims 1-3 and 5-45 are pending and will be examined.

### *Claim Objections*

2. Claims 13, 26 and 42 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

A) Claim 13, dependent from claim 10, is drawn to the PCR amplifying step being accomplished using a polymerase. However, PCR requires the presence of a polymerase, therefore this claim does not further limit claim 10.

B) Claim 26, dependent from claim 21, is drawn to the PCR amplifying step being accomplished using a polymerase. However, PCR requires the presence of a polymerase, therefore this claim does not further limit claim 21.

C) Claim 42, dependent from claim 38, is drawn to the PCR amplifying step being accomplished using a polymerase. However, PCR requires the presence of a polymerase, therefore this claim does not further limit claim 38.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 1-3, 5-9, 11, 14, 21-29, 32 and 38-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 1 is indefinite because it is not clear whether the preamble and the last method step are in agreement. The preamble step states that the method is “for amplifying a transcriptionally-active polynucleotide”. However, the first amplification step does not amplify a transcriptionally-active molecule, since the promoter and terminator are added in step three (joining). Therefore, it seems that only step four amplifies transcriptionally-active molecule, which is the third DNA fragment.

B) Claim 7 is indefinite over the recitation of “wherein said PCR amplifying comprises the addition of a binding moiety”. It is not clear where to the binding moiety is added. Is it added to the reaction mixture or to the nucleic acid ?

C) Claim 11 is indefinite over the recitation of “specifically complementary”. Applicants did not define this term, therefore it is not clear whether “not specifically complementary” means that only one base pair difference would satisfy the requirement.

D) Claim 21 is indefinite over the recitation of “a product nucleic acid fragment that comprises one or more functional nucleic acid regions joined to the polynucleotide target sequence” in step four (emphasis added). In step three of the method, third and fourth nucleic acid fragments are added to the reaction, and either one or both of these fragments comprise a region that confers function, therefore at the most the final product can have only two functional nucleic acid regions.

E) Claim 23 recites the limitation "said functional nucleic acid fragment" in line 1/2. There is insufficient antecedent basis for this limitation in the claim.

F) Claim 24 is indefinite over the recitation of “a set of primers comprising one or more nuclease resistant, binding moieties”. It is not clear whether the one or more nuclease resistant moieties are present on each primer or whether there is one moiety per primer.

G) Claim 34 is indefinite over the recitation of “nucleic acid fragments comprise a promoter and/or a terminator”. It is not clear whether each of the fragments comprises a promoter and a terminator, or whether the promoter is present on one fragment and a terminator on another.

H) Claim 38 is indefinite over the recitation of “one of the target sequences linked to at least one transcriptionally-functional region” in step four (emphasis added). In step three of the method, transcriptionally-functional fragment pairs are added to the reaction, and either one or both of these fragments comprise a transcriptionally-functional region, therefore at the most the final product can have only two transcriptionally-functional nucleic acid regions.

I) Claim 44 is indefinite over the recitation of “functional nucleic acid molecule” in the preamble. It is not clear what is meant by this term, and Applicants did not provide a definition of a “functional nucleic acid molecule”.

J) Claim 44 is indefinite over the recitation of “a nucleic acid molecule that comprises one or more functional nucleic acid regions joined to the polynucleotide target sequence “ in step four (emphasis added). In step three of the method, third and fourth nucleic acid fragments are added to the reaction, and either one or both of these fragments comprise a region that confers function, therefore at the most the final product can have only two functional nucleic acid regions.

K) Claims 5, 14, 27, 32 and 43 are indefinite over the recitation of “a non blunt end polymerase”. It is not clear what is meant by this term, and Applicants did not provide its definition. It is not clear whether “non blunt end” refers to the lack of blunt ends in the target, primers or a product of the polymerase reaction.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Before proceeding with the rejections, it is noted that the term “nucleic acid sequence that confers function” is interpreted in its broadest meaning, i.e., any function that can be assigned to a nucleic acid. Because of the lack of its definition, the term “non blunt end” is applied to any polymerase.

7. Claims 10, 11, 13 and 16 are rejected under 35 U.S.C. 102(a) as being anticipated by Cassata et al. (Gene, vol. 212, p. 127-135, May 1998).

Regarding claim 10, Cassata et al. teach construction of a promoter-gfp reporter gene to examine expression of the *C. elegans* homeobox gene *ceh-38*, but can be used to fuse any promoter sequence to any gene or its fragment. The promoter region (= target sequence) was first amplified with a first and second primers, both of which had regions complementary to the target sequence and extension regions. The 3' primer (= a first nucleic acid fragment) had the extension region complementary to a part of a nucleic acid encoding a reporter gene (= sequence that confers function). After synthesis, the promoter fragment was contacted with a linearized vector containing a sequence complementary to the extension region and PCR-amplified, producing a promoter-reporter gene nucleic acid construct (Figure 1; page 129, the last paragraph, continuing on page 130).

Regarding claim 11, Cassata et al. teach primers with extension regions not complementary to the target sequence (Fig. 1).

Regarding claim 13, Cassata et al. teach amplification using a polymerase (page 128, sixth paragraph).

Regarding claim 16, Cassata et al. teach matching the extra A added by the polymerase in the junction primer in fill-in PCR (page 132, the end of the second paragraph).

8. Claims 1, 2, 5, 6, 10, 12-15, 21, 22, 26-29 and 30-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Prodromou et al. (Protein Engineering, vol. 5, pp. 827-829 (1992)).

Regarding claims 1, 2, 10, 12, 21, 22 and 29, Prodromou et al. teach synthesis of human lysozyme gene by recursive PCR from ten oligonucleotide fragments. The oligonucleotides were 54-86 bases long and contained overlaps of 17-20 bp in length. Therefore, each of the fragments served as a primer for the neighboring fragments (Fig. 1). The 5'-most fragment contained the promoter sequence and the 3'-most fragment contained the terminator sequence (Fig. 2, page 828). Therefore, at any point during the amplification reaction, each fragment, except for fragments 1, 2, 9 and 10, is contacted sequentially with two sets of primers, both of which contain regions complementary to the fragment and extension regions, to which the next two primers anneal. For example, in an idealized situation (because in reality all of the intermediates are present at once), a fragment synthesized from fragments 3-8 is amplified with fragments 2 and 9, which have regions complementary to fragments 3 and 8, and extension regions. The resulting product is contacted with fragments 1 and 10, with fragment 1 having a region complementary to the extension region of fragment 2 and comprising a promoter sequence, and fragment 10 having a region complementary to the extension region of fragment 9 and comprising a terminator sequence. The final product is a

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fully transcriptionally-functional gene, which is further amplified by a pair of external primers (Fig. 1; page 827, 828, page 829, first paragraph).

Regarding claims 30 and 34, Prodromou et al. teach a reaction mixture (= system for adding a nucleic acid fragment that confers function to a polynucleotide sequence) that contained the oligonucleotide fragments, with two of the oligonucleotides containing regions which confer function, i.e., a promoter and a terminator sequence.

Regarding claims 5, 6, 13-15, 26-28 and 31-33, Prodromou et al. teach amplification using a Vent or Taq polymerase (page 829, first and second paragraphs).

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 3, 20, 23 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prodromou et al. as applied to claims 1, 10, 21 and 30 above, and further in view of Felgner et al. (U. S. Patent No. 6,165,720; cited in the IDS).

A) Claim 3 is drawn to the promoter-containing sequence and the terminator-containing sequence comprising a PNA-binding domain. Claim 20 is drawn to the third nucleic acid comprising a PNA binding domain. Claim 23 is drawn to the final nucleic acid product comprising a PNA binding domain. Claim 35 is drawn to nucleic acid fragments comprising PNA binding domain.



B) The teachings of Prodromou et al. are described above. Prodromou et al. teach insertion of binding domains (restriction enzyme binding sites) into the amplified product, but do not teach insertion of the PNA-binding domain.

C) Felgner et al. teach construction of nucleic acid vectors (or plasmids) containing PNA-binding sites (col. 12, lines 46-67; col. 13, lines 1-26; col. 26, lines 64-67; col. 27, 28; Fig. 8). The PNA-binding sites confer the following properties onto the plasmids: increased transfection efficiency, nuclear localization, transcription activation, endosomal lytic activity and immunostimulatory activity (col. 6, lines 29-47).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have added PNA-binding sites of Felgner et al. to transcriptionally-active nucleic acids of Prodromou et al. The motivation to do so, provided by Felgner et al. would have been that binding of PNA clamps to PNA-binding sites provided nuclease resistance to DNA duplexes (col. 6, lines 48-54).

11. Claims 7, 8, 17, 18, 24, 25, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prodromou et al. as applied to claims 1, 10, 21 and 30 above, and further in view of Uhlman et al. (U. S. Patent No. 6,063,571).

A) Claim 7 is drawn to the PCR amplification comprising the addition of a binding moiety, claim 8 is drawn to the moiety comprising a PNA molecule. Claim 17 is drawn to the amplification of a second nucleic acid fragment with an additional primer comprising a nuclease resistant binding moiety, claim 18 is drawn to the nuclease resistant binding moiety comprising a PNA molecule. Claim 24 is drawn to the amplification of an intermediate nucleic acid fragment with additional primers comprising one or more nuclease resistant binding moieties, claim 25 is drawn to the nuclease resistant binding moieties comprising a PNA molecule or one or more phosphorothioate

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molecules. Claim 36 is drawn to the amplification system further comprising an additional primer pair comprising at least one nuclease resistant binding moiety, claim 36 is drawn to the nuclease resistant binding moiety being either a PNA molecule or a phosphorothioate molecule.

B) The teachings of Prodromou et al. are described above. Prodromou et al. teach insertion of binding domains (restriction enzyme binding sites) into the amplified product, but do not teach PNA molecules which confer nuclease resistance.

C) Uhlman et al. teach amplification of nucleic acids with DNA/PNA primers, which contain a PNA moiety at the 5' end of the primer. Such primers can be used with temperature-stable polymerases (col. 2, lines 30-49; col. 5, lines 8-46). Uhlman et al. teach that nucleic acid fragments amplified with DNA/PNA primers are resistant to exonucleases (col. 1, lines 32-39).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have used the DNA/PNA primers of Uhlman et al. in the amplification method of Prodromou et al. The motivation to do so, provided by Uhlman et al., would have been that PNA confers nuclease resistance to a DNA attached to it (col. 1, lines 32-39).

12. Claims 7, 9, 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prodromou et al. as applied to claims 1, 10, 21 and 30 above, and further in view of Goodchild (Bioconjugate Chemistry, vol. 1, pp. 165-187, 1990).

A) Claim 7 is drawn to the PCR amplification comprising the addition of a binding moiety, claim 8 is drawn to the moiety comprising at least one phosphorothioate. Claim 17 is drawn to the amplification of a second nucleic acid fragment with an additional primer comprising a nuclease resistant binding moiety, claim 19 is drawn to the nuclease resistant binding moiety comprising at least one phosphorothioate.

B) The teachings of Prodromou et al. are described above. Prodromou et al. teach insertion of binding domains (restriction enzyme binding sites) into the amplified product, but do not teach addition of at least one phosphorothioate during the amplification reaction.

C) Goodchild teaches oligonucleotides modified with phosphorothioates and nuclease resistance of such oligonucleotides (page 167, the last paragraph, continued on page 168; page 170, paragraphs 3-6; page 175, paragraphs 9-11).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have used phosphorothioate-modified oligonucleotides of Goodchild as primers in the amplification reaction of Prodromou et al. The motivation to do so, provided by Goodchild, would have been that phosphorothioates provided nuclease protection to nucleic acids.

13. Claims 38-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prodromou et al. and Mullis et al. (U.S. Patent No. 4,965,188).

A) Regarding claims 38-41, Prodromou et al. teach synthesis of human lysozyme gene by recursive PCR from ten oligonucleotide fragments. The oligonucleotides were 54-86 bases long and contained overlaps of 17-20 bp in length. Therefore, each of the fragments served as a primer for the neighboring fragments (Fig. 1). The 5'-most fragment contained the promoter sequence and the 3'-most fragment contained the terminator sequence (Fig. 2, page 828). Therefore, at any point during the amplification reaction, each fragment, except for fragments 1, 2, 9 and 10, is contacted sequentially with two sets of primers, both of which contain regions complementary to the fragment and extension regions, to which the next two primers anneal. For example, in an idealized situation (because in reality all of the intermediates are present at once), a fragment synthesized from fragments 3-8 is amplified with fragments 2 and 9, which have regions complementary to fragments 3 and 8, and extension regions. The resulting product is contacted with fragments 1 and 10, with

fragment 1 having a region complementary to the extension region of fragment 2 and comprising a promoter sequence, and fragment 10 having a region complementary to the extension region of fragment 9 and comprising a terminator sequence. The final product is a fully transcriptionally-functional gene, which is further amplified by a pair of external primers (Fig. 1; page 827, 828, page 829, first paragraph).

Regarding claims 42 and 43, Prodromou et al. teach amplification using a Vent or Taq polymerase (page 829, first and second paragraphs).

B) Prodromou et al. do not teach amplification of more than one target nucleic acid.

C) Mullis et al. teach that in polymerase chain reaction more than one target nucleic acid can be amplified using primers specific for each target (col. 3, lines 1-67; col. 4, lines 1-5; col. 13, lines 20-30). The primers may have sequences non-complementary to the target attached at the 5' end of the primers, and the non-complementary sequences may contain promoters, linkers, coding sequences, etc. (col. 6, lines 44-53; col. 19, lines 60-67; col. 20, lines 1-6).

It would have been *prima facie* obvious to one of ordinary skill in the art to have amplified more than one target nucleic acid according to Mullis et al. in the method of gene synthesis of Prodromou et al. The motivation to do so, provided by Mullis et al., was that multiple fragments could be produced in large quantities in a short period of time.

14. Claims 44 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prodromou et al. and Uhlman et al. (U. S. Patent No. 6,063,571).

Regarding claims 44 and 45, Prodromou et al. teach synthesis of human lysozyme gene by recursive PCR from ten oligonucleotide fragments. The oligonucleotides were 54-86 bases long and contained overlaps of 17-20 bp in length. Therefore, each of the fragments served as a primer for the neighboring fragments (Fig. 1). The 5'-most fragment contained the promoter sequence and

the 3'-most fragment contained the terminator sequence (Fig. 2, page 828). Therefore, at any point during the amplification reaction, each fragment, except for fragments 1, 2, 9 and 10, is contacted sequentially with two sets of primers, both of which contain regions complementary to the fragment and extension regions, to which the next two primers anneal. For example, in an idealized situation (because in reality all of the intermediates are present at once), a fragment synthesized from fragments 3-8 is amplified with fragments 2 and 9, which have regions complementary to fragments 3 and 8, and extension regions. The resulting product is contacted with fragments 1 and 10, with fragment 1 having a region complementary to the extension region of fragment 2 and comprising a promoter sequence, and fragment 10 having a region complementary to the extension region of fragment 9 and comprising a terminator sequence. The final product is a fully transcriptionally-functional gene, which is further amplified by a pair of external primers (Fig. 1; page 827, 828, page 829, first paragraph).

B) Prodromou et al. teach insertion of binding domains (restriction enzyme binding sites) into the amplified product, but do not teach PNA molecules which confer nuclease resistance.

C) Uhlman et al. teach amplification of nucleic acids with DNA/PNA primers, which contain a PNA moiety at the 5' end of the primer. Such primers can be used with temperature-stable polymerases (col. 2, lines 30-49; col. 5, lines 8-46). Uhlman et al. teach that nucleic acid fragments amplified with DNA/PNA primers are resistant to exonucleases (col. 1, lines 32-39).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have used the DNA/PNA primers of Uhlman et al. in the amplification method of Prodromou et al. The motivation to do so, provided by Uhlman et al., would have been that PNA confers nuclease resistance to a DNA attached to it (col. 1, lines 32-39).

### *Double Patenting*

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 1, 2, 7, 8, 10, 11, 16 and 21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 6, 7, 10 and 12 of U.S. Patent No. 6,280,977 B1 (Liang et al.).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claims. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other because independent claims 1 and 7 of the '977 patent are species of the independent claims 1, 10 and 21 of the current application. In other words, claims 1 and 7 of the '977 patent fall entirely within the scope of claims 1, 10 and 21 of the current application, therefore claims 1, 10 and 21 are anticipated by claims 1 and 7 of the '977 patent. Specifically, the methods of claims 1 and 7 differ from the methods of the current application in the following manner:

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- for claim 1, the only difference is the presence of a thymidine base immediately preceding a region of complementarity between a third primer (= promoter-containing sequence) and an F1 fragment (claim 1 of the '977 patent) or fourth primer (=terminator-containing sequence) and an F2 fragment,
- for claim 10, the difference is the presence of two function-conferring primers, the functions being a promoter and a terminator,
- for claim 21, the difference is that functional regions are a promoter and a terminator.

Therefore, claims 1 and 7 of the '977 patent anticipate claims 1, 10 and 21 of the current application.

17. No claims are allowed.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (703) 306-5877. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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May 18, 2003

Teresa Strzelecka, Ph. D.

Patent Examiner

*Teresa Strzelecka*

*5/18/03*